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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,779

09/28/2007

Michael Teifel

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EXAMINER

SAJJADI, FEREDYDOUN GHOTB

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,779	<b>Applicant(s)</b> TEIFEL ET AL.	
	<b>Examiner</b> FEREYDOUN G. SAJJADI	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION**

Claims 1-35 are pending in the Application, following the preliminary amendment dated June 14, 2006. MPEP 2173.05(q) states: Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness under 35 U.S.C. 112, second paragraph. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986); and would further be rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

1. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, 19-31, 33 and 35 drawn to a method of manufacturing a pharmaceutical composition comprising a cationic liposomal preparation.

Group II, claim(s) 1-35, drawn to a method of administering or treating a patient with a pharmaceutical composition comprising a cationic liposomal preparation.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature, which is shared by Groups I and II, is a cationic liposomal preparation comprising paclitaxel and

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a neutral lipid. Groups I and II do not share a special technical feature over the art because the preparation was previously known in the prior art, as evidenced by McDonald et al. (WO 01/017508; Published 15 March 2001; of record), disclosing cationic liposomes containing taxanes such as paclitaxel, that inhibit angiogenesis and useful in treating tumors (p. 21, lines 1-5), and may further comprise neutral lipids (p. 19, lines 13 and 14).

It should be noted that Groups I and II claims are drawn to distinct methods that require distinct method steps and are further directed to different goals, having non-shared particulars, requiring non-coextensive search and examination of their respective subject matter. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I and II do not relate to a single inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Treatments that include wound healing, rheumatoid arthritis, dermatitis, psoriasis and endometriosis, pancreatic cancer, inoperable pancreatic cancer, gastro-intestinal cancer, lung cancer, colorectal or gastric cancer, breast cancer, prostate cancer and melanoma, as recited in claims 16 and 32.

Active agents that include a specific anti-tumor, anti-endothelial cell active substance, a chemotherapeutic agent, an immunological active substance, a chemosensitizer, a taxane, a camptothecin, a statin, a depsipeptide, thalidomide, discodermolide, laulimalide, isolaulimalide, eleutherobin, Sarcodictyin A and B, paclitaxel, docetaxel, cisplatin, carboplatin, camptothecin, doxorubicin, 5-fluorouracil, gemcitabine, steroids, antihistamines, H2 receptor antagonists, Ranitidine, Dexamethasone, Diphenhydramine, Famotidine, Hydrocortisone, Clemastine, Cimetidine, Prednisolone, Chlorpheniramine, Chlorphenamine, Dimethindene maleate, Promethazine, verapamil and protamine, as recited in claims 24 and 26-31.

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Applicant is required, in reply to this action, to elect a single specific species for each of treatments and active agents, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 1, 9, 17, 22 and 35, and claims dependent therefrom.

The following claim(s) are generic: 1-35.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

As the technical features of wound healing, rheumatoid arthritis, dermatitis, psoriasis and endometriosis, pancreatic cancer, inoperable pancreatic cancer, gastro-intestinal cancer, lung cancer, colorectal or gastric cancer, breast cancer, prostate cancer and melanoma, anti-tumor, anti-endothelial cell active substance, a chemotherapeutic agent, an immunological active substance, a chemosensitizer, a taxane, a camptothecin, a statin, a depsipeptide, thalidomide, discodermolide, laulimalide, isolaulimalide, eleutherobin, Sarcodictyin A and B, paclitaxel, docetaxel, cisplatin, carboplatin, camptothecin doxorubicin, 5-fluorouracil, gemcitabine, steroids, antihistamines, H2 receptor antagonists, Ranitidine, Dexamethasone, Diphenhydramine, Famotidine, Hydrocortisone, Clemastine, Cimetidine, Prednisolone, Chlorpheniramine, Chlorphenamine, Dimethindene maleate, Promethazine, verapamil and protamine linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/  
Primary Examiner, Art Unit 1633

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